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DIRAMIO, JACQUELINE A	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,976	SONG, XUEDONG	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *7,18 and 21-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/27/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 1 and 14 are acknowledged.

Currently, claims 1 – 6, 8 – 17, 19 and 20 are pending and under examination. Claims 7, 18 and 21 – 38 are acknowledged as withdrawn as drawn to non-elected inventions.

Withdrawn Rejections

The previous rejection of claim 1 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment filed October 1, 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 3, 5, 6, 12 – 15, 17 and 20 are rejected under 35 U.S.C. 102(e) as being unpatentable over Daniels et al. (US 2006/0008921), as evidenced by Fitzpatrick et al. (US 6,121,008).

Daniels et al. teach a flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample, said flow-through assay device comprising a porous membrane, said porous membrane being in communication with detectable labels (detection probes) and positive controls (calibration probes), said detectable labels being conjugated with a ligand (specific binding member) for the analyte, said porous membrane defining:

a capture region (detection zone) within which is immobilized a first capture reagent, said first capture reagent being configured to bind to at least a portion of said conjugated detectable labels or complexes formed between the analyte and said conjugated detectable labels to generate a detection signal having an intensity;

a control region (compensation zone) located downstream from said capture region, wherein a control ligand (second capture reagent) is immobilized within said control region, said control ligand being configured to bind to said conjugated detectable labels, particularly those remaining unbound to the analyte, and excess complexes formed between said analyte and said conjugated detectable labels passing through said detection zone to generate a control signal having an intensity; and

an independent control region (calibration zone) within which an independent control reagent (third capture reagent) is immobilized, said control reagent configured to bind to said positive control to generate a signal that is substantially constant relative to the intensities of said detection signal and said control signal;

wherein the amount of analyte is determined by measuring the signals generated in the various regions (see Figure1; and paragraphs [0016], [0020]-[0029], [0108], [0111]-[0120], [0135], [0136], [0180], [0183]-[0188], [0202], and [0203]).

With respect to the limitation of Applicant's claim 1, "wherein the intensity of the calibration signal is inversely proportional to the intensity of said detection signal," the signal generated in the control region of Daniels et al. would create a signal that is inversely proportional to the intensity of the detection signal because the control region is binding to the unbound conjugated detectable labels, wherein the amount of unbound detectable labels would be inversely proportional to the amount of analyte in the test sample. Since the capture region is binding to the complexes created between the analyte and the detectable label, the detection signal would be proportional to the amount of analyte in the sample. Therefore, the control signal created in the control region of Daniels et al. would in fact be inversely proportional to the detection signal created in the capture region (see Fitzpatrick et al.: column 2, lines 19-67; and column 3, lines 1-9).

With respect to Applicant's claims 2-3 and 15, the detectable label is preferably a semiconductor nanocrystal, which represents a luminescent compound (see paragraphs [0080], [0083], [0097], [0108] and [0111]).

With respect to Applicant's claim 5, the ligand (specific binding member) is preferably an antibody (see paragraphs [0111] and [0135]-[0137]).

With respect to Applicant's claims 6 and 17, the capture reagent preferably comprises an antibody (see paragraph [0180]).

With respect to Applicant's claims 12 and 20, the independent control reagent comprises a member of a specific binding pair, which can include antigens and antibodies (see paragraphs [0090]-[0092], and [0186]-[0188]).

With respect to Applicant's claim 13, the device can comprise a sandwich-type assay device (see Figure 1; and paragraph [0072]).

With respect to Applicant's claim 14, the limitations of this claim are discussed above with respect to Applicant's claim 1. Further, the limitation requiring the detection probes and calibration probes to be "optical" is taught by Daniels et al., wherein the detectable label and positive control label comprise semiconductor nanocrystals (see paragraphs [0080], [0108], [0111], [0186] and [0187]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Kang et al. (US 5,656,448).

The Daniels et al. reference, which is discussed in the 102(e) rejection above, fails to teach that the conjugated detection labels (probes) comprise a visual label.

Kang et al. teach a dipstick immunoassay device for detection of analytes in a sample of biological fluid. The device utilizes an immunological component that is immobilized in a test zone, wherein the immunological component is capable of binding to a target analyte. The device further utilizes an enzyme-labeled antibody, which also binds to the target analyte, wherein a sandwich complex is created in the test zone between the target analyte, enzyme-labeled antibody, and immobilized immunological component in the test zone when the target analyte is present in the test sample. The antibodies that are labeled via the enzymes can also be labeled with a direct label (visual label), such as a metal sol, non-metal sol, dye sol, latex particle, or a liposome. The direct labels, unlike enzyme labels, produce a visually discernable signal by virtue of their concentration and not by way of a chemical interaction (see Figures; Abstract; column 2, lines 28-67; column 3, lines 1-20 and lines 60-65; and column 5, lines 1-16 and lines 36-47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device and labels of Daniels et al. the use of a visual or direct label as taught by Kang et al. because Kang et al. teach the benefit of utilizing a direct label because direct labels produce a visually discernable signal by virtue of their concentration and not by way of a required interaction.

Claims 8 – 11 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Jou et al. (US 5,670,381).

Daniels et al. further fail to teach that the capture reagent, i.e. control ligand, immobilized in the control region (compensation zone) comprises a polyelectrolyte.

Jou et al. teach a device for performing an assay comprising a porous material containing a capture or reaction zone with an immobilized capture reagent. The device utilizes a specific binding member attached to a charged substance that is contacted with an analyte of interest to form a complex. The complex binds to the immobilized capture reagent in the capture or reaction zone through ion-capture, wherein the capture reagent is oppositely charged with respect to the charged substance of the analyte complex. The capture reagent preferably comprises an anionic or cationic polymeric substance (polyelectrolyte), which enables the production of a generic solid phase device for use in specific binding assays. Assay procedures for many different analytes can use the same solid phase material which contains a predetermined zone of anionic or cationic capture polymer rather than an immobilized binding member capable of binding only a specific analyte as found in conventional flow-through or test-strip devices. Further, the ion-capture technique increases the potential number of complexes that can be immobilized on the solid support (see column 6, lines 25-40; column 7, lines 1-46; column 10, lines 63-65; column 19, lines 29-67; column 22, lines 29-67; and column 23, lines 1-26).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Daniels et al. a polyelectrolyte

as the capture reagent in the control region (compensation zone) as taught by Jou et al. because Jou et al. teach the benefit of using an anionic or cationic polymeric substance as the immobilized capture reagent in a capture zone because the polymeric substance allows for the binding of a conjugated substance or complex to a solid phase support material through ion-capture, which increases the potential number of complexes that can be immobilized on the solid support and allows for the production of a generic solid phase device, wherein many different analytes can use the same solid phase material which contains a predetermined zone of anionic or cationic capture polymer rather than an immobilized binding member capable of binding only a specific analyte as found in conventional flow-through or test-strip devices.

With respect to Applicant's claims 9 and 11, Jou et al. teach that the charged polymeric substance (polyelectrolyte) can be anionic or cationic (see column 7, lines 1-46; and column 19, lines 29-36).

With respect to Applicant's claim 10, Jou et al. teach various charged polymers for the polyelectrolyte, which include combinations of those recited in Applicant's claim 10 (see column 19, lines 29-67; and column 20, lines 1-67).

Response to Arguments

Applicant's arguments filed October 1, 2007 have been fully considered but they are not persuasive. In particular, Applicant argues (see p6-7) that the applied reference of Daniels et al. (US 2006/0008921) does not anticipate Applicant's claimed invention

because the reference fails to teach Applicant's amendment to claims 1 and 14 requiring the capture reagent in the compensation zone (control region of Daniels et al.) to be configured to bind to both the conjugated detection probes **and** complexes formed between the analyte and the conjugated detection probes. However, this argument is not found persuasive because the control region (compensation zone) of Daniels et al., which is configured to bind the unbound conjugated detectable labels is also capable of binding any excess detection complex, i.e. complexes formed between the analyte and the conjugated detectable label (see paragraph [203] in particular). Therefore, because Daniels et al. do in fact teach Applicant's amended limitation to claims 1 and 14, the reference still anticipates Applicant's claimed invention.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jackie DiRamio
Patent Examiner
Art Unit 1641

LONG V. LE 11/06/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600